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(71) Applicant *(for all designated States except US)*: ASN RESPIRATION DEVICE LTD. [IL/IL]; Technology Center, 20179 Misgav (IL).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: OREN, Nathan [IL/IL]; 56 Morad Hagay, 21752 Carmiel (IL).

(74) Agent: COHEN ZEDEK & RAPAPORT; 29 Bezalel Street, 64683 Tel-Aviv (IL).

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(54) Title: RESPIRATION DEVICE

(57) Abstract

A respiration mask to prevent sleep apnea and snoring comprising means for measuring the real time pressure inside the mask, and means for maintaining a predetermined pressure inside the mask. The mask is self-contained and does not require external air compression means.

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RESPIRATION DEVICE

The present invention relates to respiration aids, particularly for use by patients suffering from the disease know as Sleep Apnea and snoring. Sleep Apnea, which manifests itself by intensive snoring during sleep, is a biological disorder of the respiratory channels, in particular the upper air passages which tend to collapse and become blocked towards the end of some exhalation cycles. In order to overcome and avoid suffocation, the patient must exert an effort to continue the breathing process, i.e. the inhalation phase, which effort entails his actual awaking. Patients are thus driven in to a serious mental and physical condition, due to accumulated lack of sleep; although the patients seem to be asleep, actually they are not deriving the benefits of slumber, not to mention the inconvenience caused by people in proximity.

In the course of research, it has been found that great relief is attained if, by some external means, the patient's lungs (and, of course, the upper bronchial passages included) are kept under a constant, slightly elevated air pressure, of the order of 5-15 cm H_2O above the ambient, "atmospheric" pressure.

Apparatus devised for the application of this kind of treatment included a belted nose-mask and snorkel, through which excessive quantity of air was supplied to the patient (of the order of 100 lit/min while normal human air consumption during sleep is about 6 lit/min).

This method assured that both the inhalation and the exhalation took place under practically the same, elevated pressure, as required. However, it has been found that the supply to the patient's mask of such extremely high quantities of air causes great inconvenience, expressed, inter alia, by extensive cooling and/or drying up of the nose and other breathing passages.

It has already been proposed to overcome this inherent deficiency of the conventional system - cf. Israel Patent Application No. 82300; however the apparatus therein disclosed still requires the installation of an electric motor to drive an indispensable compressor.

It is, therefore, the prime object of the present invention to provide a respiration device for the above purpose which is self-contained, and does not require an electrically powered air compressor.

The device of the invention is a respiration aid device, particularly for preventing snoring and Sleep Apnea, comprising a nose cover, a one-way inhalation, air valve, an exhalation controlled air, valve, a potentiometer for setting of in-mask pressure, a pressure gauge, two analog-to-digital (A/D) :uits, comparator, a controller.

The invention is illustrated in Fig. 1. Nothing in the following description is meant to limit the scope of the invention; it is meant only to clarify and illustrate it.

The device of the invention comprises a mask covering the patient's nose, and a servo mechanism maintaining inside the mask a desired pressure during exhalation. This pressure inside the mask is due to the patient's exhalation only.

As illustrated the novel device comprises a mask 1 to be attached to the face by means of a strap around the head. There are provided two valves, and inflow valve (2) and an outflow valve 3, which, allow air to flow from the outside into the mask and from the mask to the outside, respectively. The opening and closing of the one-way inflow valve is controlled by that valve's mechanism; the opening and closing of the outflow valve are controlled by control means 8.

There is provided a pressure gauge (5) which senses the air pressure inside the mask. A potentiometer (4) is set so that its resistance is used as reference. This reference corresponds to the desired threshold value of air pressure. Units marked on a scale, for setting the potentiometer, are units of pressure, given in mm of water above atmospheric pressure, in the range of 0 to 150 mm. There is provided two A/D converters (6 and 6') one for the air-pressure information coming from the pressure gauge and the other receiving reference information coming from potentiometer (4), convert these two analog data into digital data: the analog pressure information into digital pressure-information, and the analog resistance information into digital reference-information. These are input to a comparator which compares them with each other. According to this comparison the comparator 7 sends information to the controller 8. If the pressure measured by the pressure gauge is higher than the set reference, the comparator 7 sends to the controller 8 information to open the outflow valve 6'. If the pressure measured by the pressure gauge is lower than the set reference, the comparator sends to the controller 8 information to keep the outflow valve 6' closed.

Both valves are very sensitive and respond rapidly to very small pressure differences.

Various outflow valve, can be used, such as:

(1) and on/off valve;

(2) a valve with variable opening: from fully closed to fully open.

During inhalation the pressure within the mask 1 is lower than the pressure corresponding to the set reference so that the outflow valve 3 is closed and the patient inhales through the inflow valve 2. During exhalation the pressure within the mask 1 builds up because the two valves are closed. When the pressure within the mask exceeds the pressure corresponding to the set reference the control 8 sends information to the outflow valve 3 to open it, allowing air to flow out.

If the outflow valve 3 is of the on/off type it remains open until the pressure within the mask 1 reaches the pressure corresponding to the set reference and the outflow valve closes. If the outflow valve 3 is of the variable-opening type it opens in proportion to the pressure within the mask so that the pressure remains at the level corresponding to the set reference, and when it drops below that threshold, the valve closes.

It will thus be readily appreciated that the device provided according to the invention, is of simple construction; needs not be associated with auxiliary installations such as an electrical power source; it comprises a small number of simple elements and is therefor not liable to wear during prolonged use, and also inexpensive.

CLAIMS

1. A respiration mask, particularly for preventing sleep Apnea and snoring, comprising:
a nose cover, provided with an inhalation, one-way, air valve; and exhalation, controlled, air valve; a potentiometer for reset timing in-mask pressure; a pressure gauge; two analog-to-digital circuits; a comparator and controller means, thus providing means for controlling the exhalation valve to maintain in-mask pressure during exhalation at a preset value.

2. A mask according to claim 1, where the opening and closing of the one-way outflow valve is controlled by control means.

3. A mask according to claim 1 or 2, where means are provided for establishing in the mask a pressure in the range of from about 0 to 150 mm water.

4. A mask where a pressure gauge senses air pressure inside the mask and a potentiometer set so that its resistance serves as reference, according to which preset difference the air pressure in the mask is maintained.

5. A system according to any of claims 1 to 4, where there are provided A/D converters, one for sensing air pressure from the pressure gauge, the other from the potentiometer, which data are used as input to a comparator which sends commands to the outflow valve, either opening it or leaving it in the closed state.

6. A respiration aid device for preventing Sleep Apnea and snoring substantially as hereinbefore described with reference to the accompanying drawing.

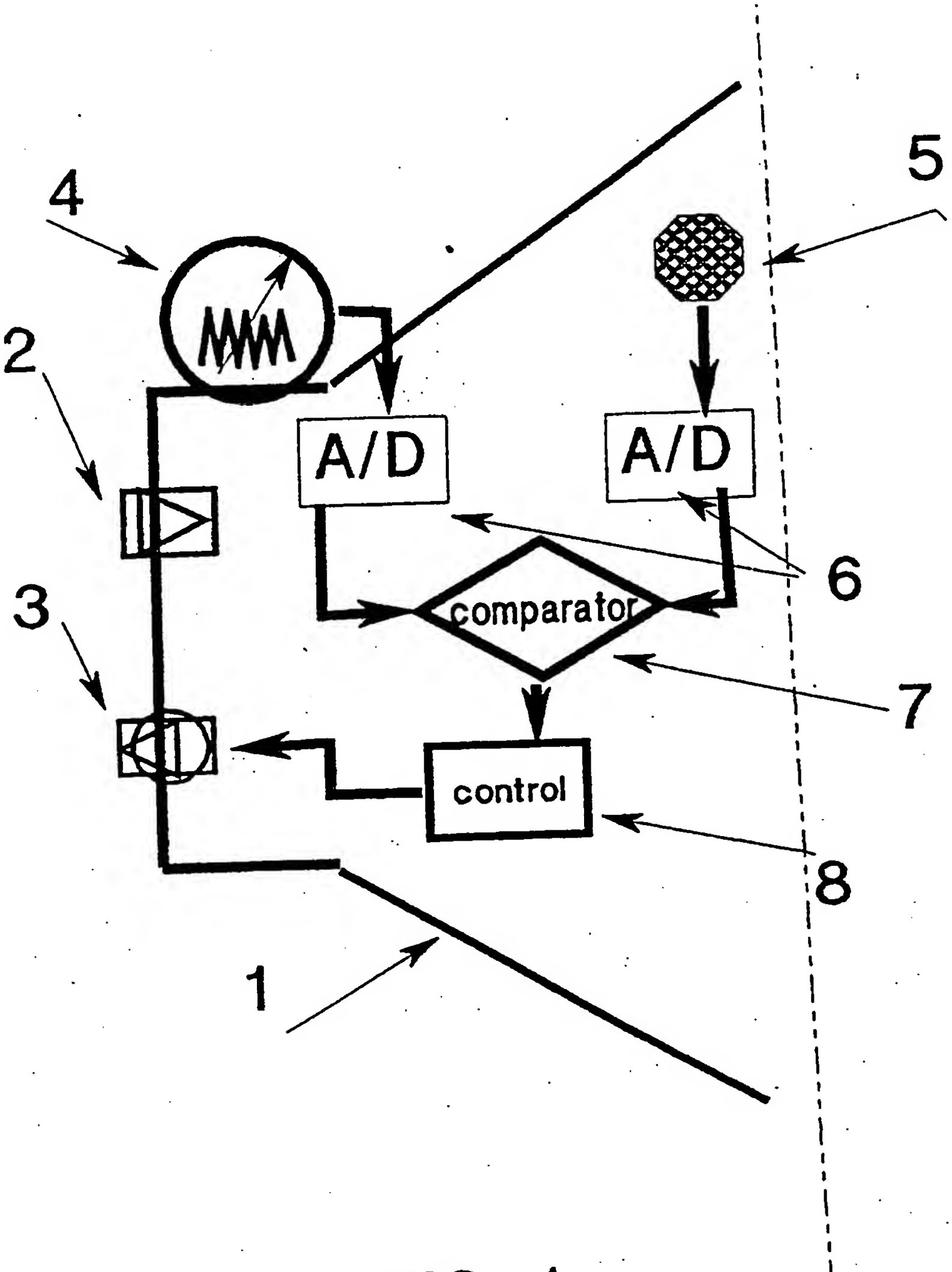

FIG. 1

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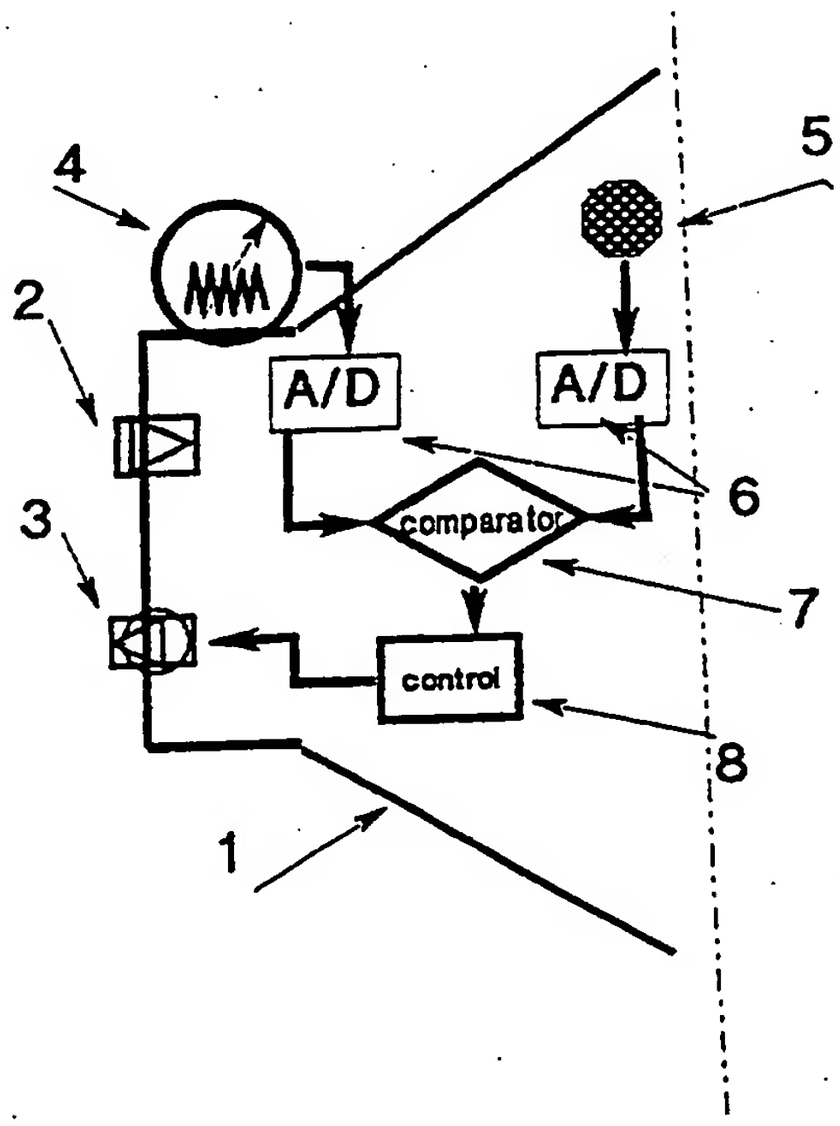
(54) Title: RESPIRATION DEVICE

(57) Abstract

A respiration mask (1) to prevent sleep apnea and snoring, comprises means (5) for measuring the real time pressure inside the mask, and means (3) (8) for maintaining a predetermined pressure inside the mask. The mask (1) is self-contained and does not require external air compression means.



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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL96/00004

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61M 16/00; A62B 7/00, 18/02
US CL :128/204.18, 204.21, 204.23, 205.25
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : U.S. CL. 128/204.18, 204.21, 204.23, 205.25

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,265,595 A (RUDOLPH) 30 November 1993, Figs. 1-3.	1-5
Y , E	US 5,572,993 A (KUROME et al) 12 November 1996, Fig. 1; and col. 7, lines 7+.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search
04 MARCH 1997

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INTERNATIONAL SEARCH REPORT

International application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 6
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claim 6 was not searched because it fails to point out what is included or excluded by the claim language.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.